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PAGE 7/12 * RCV'D AT 8/26/2008 9:55:58 AM [Eastern Daylight Time] * SVR:USPTO-EFRM-6/12 * DMS:2738300 * CSID: * DURATION (mm:ss):03:48

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REMARKS

Claims 1, 3 and 7-17 are currently pending in the subject patent application and are currently under consideration. Claims 1, 10 and 13 have been amended herein to expedite allowance of the subject patent application in view of the Examiner's 35 USC 112 rejection. Support for the amendments to claims 1, 10 and 13 can be found at, for example, at page 5, lines 1-7 of the instant specification. Favorable reconsideration is respectfully requested in view of the comments and amendments herein.

I. **Petition Pursuant to 37 CFR 1.137(b)**

Applicant's representative respectfully request revival of the subject patent application in view of the comments herein. Recourse is being sought under 37 CFR 1.137(b), which states:

"If the delay in reply by applicant or patent owner was unintentional, a petition may be filed pursuant to this paragraph to revive an abandoned application, a reexamination prosecution terminated under §§ 1.550(d) or 1.957(b) or limited under § 1.957(c), or a lapsed patent. A grantable petition pursuant to this paragraph must be accompanied by:

- (1) The reply required to the outstanding Office action or notice, unless previously filed;
- (2) The petition fee as set forth in § 1.17(m);
- (3) A statement that the entire delay in filing the required reply from the due date for the reply until the filing of a grantable petition pursuant to this paragraph was unintentional. The Director may require additional information where there is a question whether the delay was unintentional; and
- (4) Any terminal disclaimer (and fee as set forth in § 1.20(d)) required pursuant to paragraph (d) of this section."

A response to the Office Action (dated December 10, 2007) was not filed on time due to clerical error. More particularly, because of the change in legal representation for Applicant, the deadline for response was inadvertently missed. Additionally, after the Examiner Interview of

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February 14, 2008, applicant's representative inadvertently did not docket for a response to be filed prior to the expiration of the statutory deadline. As a result, we unintentionally missed the deadline, as confirmed by the Examiner in the Notice of Abandonment and during our telephone conversation of June 19, 2008. Applicant's representative maintains that the entire delay in filing the required reply from the due date for the reply until the filing of a grantable petition was unintentional. Further, upon receiving the Notice of Abandonment on July 10, 2008, assignee has reviewed the cited prior art and prepared comments and amendments that appear to overcome the cited prior art. Accordingly, we believe that the subject patent application is now in condition for allowance.

II. Rejection of Claims 1, 3 and 7-17 Under 35 U.S.C. §112

Claims 1, 3 and 7-17 stand rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. More specifically, the Examiner asserts that the claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention. Applicant's representative respectfully disagrees. The amendments to independent claims 1, 10 and 13, are supported by the instant specification at page 5, lines 1-7. More particularly, the claimed "inserting at least a first cultured connective tissue construct" is supported at page 5, line 2, which states "one or more pieces may be used to plug the hole with the pieces held in place by pressure imposed by the surrounding tissues. Accordingly, this rejection should be withdrawn.

III. Rejection of Claims 1, 3 and 7-17 Under 35 U.S.C. §103(a)

Claims 1, 3 and 7-17 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Stovall (WO 99/04720) in view of Murphy *et al.* (WO 00/29553) and further in view of Lambrecht *et al.* (US 7,220,281). Applicant's representative respectfully requests that this rejection be withdrawn for at least the following reasons. The cited references, either alone or in combination, fail to teach or suggest all aspects set forth in the subject claims.

To reject claims in an application under §103, an examiner must establish a *prima facie* case of obviousness. A *prima facie* case of obviousness is established by a showing of three basic criteria.

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First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second there must be a reasonable expectation of success. *Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations.* See MPEP §706.02(j). The teaching or suggestion to make the claimed combination and the reasonable expectation of success must be found in the prior art and not based on the Applicant's disclosure. See *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991) (emphasis added).

The claimed invention relates to uses of cultured living connective tissue constructs in surgical repair indications. In particular, amended independent claim 1 recites a method for repairing an intervertebral disc of a patient using a cultured connective tissue construct, comprising: forming at least one opening in the annulus fibrosis of the intervertebral disc; removing at least a portion of the nucleus pulposus through the opening in the annulus fibrosis; *inserting at least a first cultured connective tissue construct into the opening of the annulus fibrosis; and grafting a second cultured connective tissue construct to close the opening in the annulus fibrosis*, wherein the cultured connective tissue constructs comprise: an extracellular matrix layer; and cultured fibroblast cells that synthesize and assemble the layer of extracellular matrix in the absence of exogenous matrix components or synthetic members. Amended independent claims 10 and 13 recite similar aspects. Stovall, Murphy *et al.* and Lambrecht *et al.* do not teach or suggest such aspects of the subject claims.

Stovall relates to treating ruptured intervertebral discs by employing polymer solutions, cells or a combination thereof in liquid form. Stovall further allows for the polymer solution, with or without chondrocytes or fibroblasts, to be injected or applied upon or within the annular fibrosis in liquid form. However, the cited reference does not allow for *inserting at least a first cultured connective tissue construct into the opening of the annulus fibrosis; and grafting a second cultured connective tissue construct to close the opening in the annulus fibrosis*, as in amended independent claim 1, let alone grafting and/or suturing the second cultured connective tissue construct to tissue surrounding the opening in the annulus fibrosis in order to close the opening, as afforded by amended independent claims 10 and 13.

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Murphy *et al.* does not compensate for the aforementioned deficiencies of Stovall. Murphy *et al.* relates to producing cultured tissue constructs. However, Murphy *et al.* is not directed towards the aspects recited in amended independent claims 1, 10 and 13, namely intervertebral disc repair and sealing of a ruptured annular fibrosis.

Lambrecht *et al.* relates to surgical treatment of intervertebral discs that have suffered from tears in the annulus fibrosis or herniation of the nucleus pulposus. The Examiner points to portions of the cited reference that allow for materials or devices to be inserted into an opening of the annulus fibrosis. However, Lambrecht *et al.* is not directed towards inserting a first device into the opening, and a second opening to close the same opening, as afforded by the amended independent claims. What is more, in view of the amendments to independent claims 1, 10 and 13, the Examiner's new matter rejection is now moot, as discussed *supra*. Therefore, since the filing date of the instant patent application precedes the filing date of Lambrecht *et al.*, the cited reference has been improperly applied for this rejection.

In view of at least the foregoing, it is readily apparent that the cited references, either alone or in combination, do not teach or suggest all aspects of the subject claims. Accordingly, this rejection should be withdrawn.

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CONCLUSION

In the event any additional fees are due in connection with this document not covered by the attached credit card payment form, the Examiner is invited to contact applicant's undersigned representative at the telephone number below.

Respectfully submitted,

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